Australian Government
Department of Health
Office of Drug Control

Commonwealth Medicinal Cannabis Initiative

Information and Consultation Sessions

11-20 July 2016

Reminder

What will be discussed?

- Please turn phones off or put on silent
- No voice or video recording
- Please keep questions for the Q&A session at the end
- Bathrooms can be found across the hallway

01

Agenda

What will be discussed?

- About ODC
- Legislation and International Conventions
- Introduction to the framework – where are we up to?
- The process
- Patients
- Manufacturers
- Cultivators
- Fees and charges
- Summary
- Questions

02

About ODC

Part of the Health Products Regulation Group of the Commonwealth Dept. of Health

- Regulates and provides advice on import, export and travelling with controlled drugs i.e. drugs the importing and exporting of which require Commonwealth approval (e.g. morphine, methadone, diazepam, dexamphetamine)
- Regulates and provides information on manufacture of controlled drugs
- Regulates medicinal cannabis cultivation to implement Australia's obligations under International Drug Conventions.
- Reporting on activities to the International Narcotic Control Board (INCB)
- Applying amendments to international drug controls in Australia

03

Domestic Legislation

Narcotic Drugs Act 1967

The *Narcotic Drugs Act 1967* provides the Commonwealth with powers to meet certain of Australia's obligations under the *Single Convention on Narcotic Drugs 1961.* This includes regulation of narcotic drug manufacture and cannabis cultivation for medicinal and related scientific purposes.

The Act was amended in in February 2016 to permit the Commonwealth to allow for cannabis cultivation for medicinal and related scientific purposes in accordance with the *Single Convention on Narcotic Drugs, 1961*

04

International Conventions

Single Convention

The Single Convention aims to combat drug abuse by coordinated international action.

It seeks to limit the possession, use, trade, distribution, import, export, manufacture and production of drugs exclusively to medical and scientific purposes. It also combats drug trafficking through international cooperation to deter and discourage drug traffickers.

Introduction to the Regulatory Framework

What has been achieved so far?

- Extensive consultations with states and territories on cultivation and patient access
- Requirements for regulations are being determined
- General process for cultivators and manufacturers is being mapped out
- Website launched – www.odc.gov.au

Introduction to the Regulatory Framework

What needs to happen before October 30

- Regulations to be finalised after approval by the Minister and Executive Council
- Guidelines for industry to be finalised
- TGA and states and territories to identify patient groups who will have access to medicinal cannabis products

International practice

What are other countries doing?

- Canada, The Netherlands and Israel are the three leading jurisdictions with mature medicinal cannabis programs

  (Medicinal cannabis in the US is regulated by some states and there is not federal-level recognition of cannabis as a medicinal product)

- Canada currently has 33 licensed cultivators
- The Netherlands has 1 cultivator operating on behalf of the government
- Israel has a small number of cultivators
- Exact production area is unknown; however, it is relatively small

International practice - comparison

According to a recent study undertaken by the University of Sydney, extrapolation of international practice indicates that to supply **20000** patients Australia-wide:

- Approximately 10-15 hectares required for broad acre crops, or
- 2 hectares of greenhouses would be required

These are preliminary figures and further research is required.

Actual patient numbers are unknown and range between 20 000 and 100 000 for four patient groups:

- Children with intractable epileptic conditions
- Spasticity in Multiple Sclerosis
- Nausea in chemotherapy in cancer and HIV/Aids treatment
- End of life palliative care in cancer patients

Brief overview of legislation in place

- A licence is required to cultivate cannabis for medicinal purposes
- Permits that set out the amounts and strains of cannabis will be needed before cultivation can begin
  - A contract with a manufacturer is required
- Up to three licences will be required for manufacturing
  - Narcotic Drugs Act
  - Therapeutic Goods Act
  - State/territory licence
- To get a Narcotic Drugs Act licence, must be able to demonstrate supply to meet demand
- Permits will control how much can be manufactured
- All licences will be subject to conditions
- All licences will be subject to compliance and monitoring
- On commencement, licences will only be issued for 1 year

What the regulations may cover

The regulations can cover such matters as:

- documentation requirements for applying for a licence
- the security that must be applied on the licensed premises
- requirements for the land and premises
- matters relating to ‘suitable persons’ as employees
- application and inspection fees, if any
- matters where the licence must not be granted
- conditions that might be applied to a licence
- provisions for suspension of licences

These remain matters for the Government to decide.

Today’s session will help in framing that advice to Government.

The Act imposes stringent guidelines

Persons and entities involved in medicinal cannabis cultivation or manufacture must meet:

- the "Fit and Proper Persons Test" for applicant and company directors
- employee suitability requirements
- financial viability requirements for applicant's capacity to comply with conditions

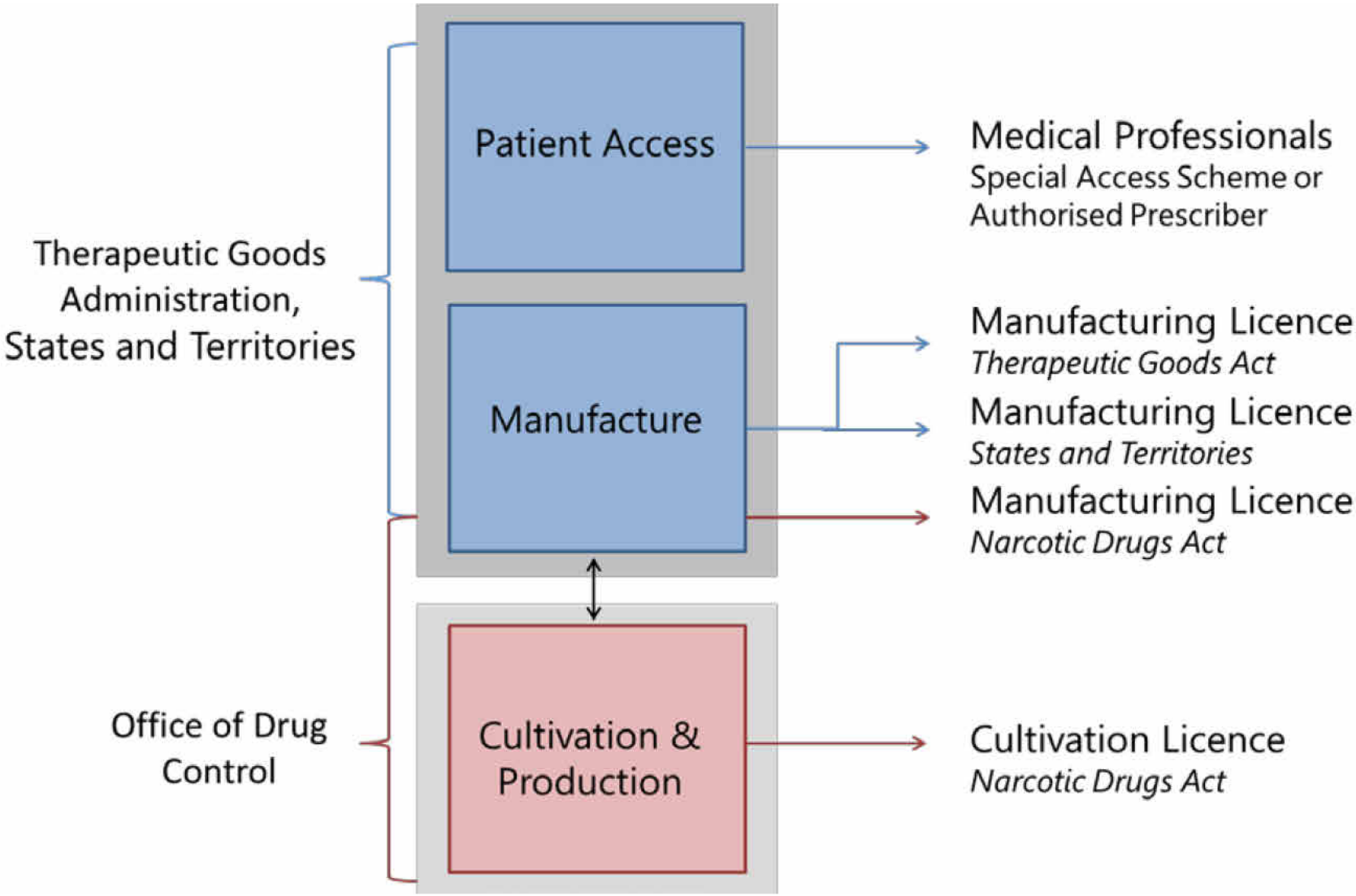
- Location of, and security for, medicinal cannabis cultivation or manufacturing sites
  - Meet site location requirements
  - Meet site security requirements

The Act imposes stringent guidelines

- Storage, handling, transport and destruction of medicinal cannabis
  - Meet secure transport requirements
  - Meet secure storage requirements
  - Meet cannabis material disposal requirements

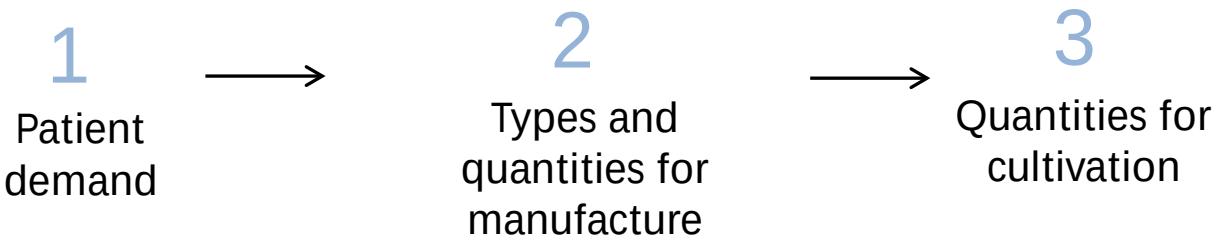
- Record keeping and auditing of medicinal cannabis activity
  - Meet record keeping and management requirements

The Process


Patient Access
Manufacture
Cultivation & Production
Therapeutic Goods Administration, States and Territories
Office of Drug Control
Medical Professionals
Special Access Scheme or Authorised Prescriber
Manufacturing Licence
Therapeutic Goods Act
Manufacturing Licence
States and Territories
Manufacturing Licence
Narcotic Drugs Act
Cultivation Licence
Narcotic Drugs Act

Patient access to medicinal cannabis products

- **To be determined** by the Therapeutic Goods Administration (TGA) as well as the states and territories
- **Access issues** to be resolved include indications (conditions), who can prescribe, and what types of medicinal cannabis products can be prescribed
- **Demand** will determine the types and quantities of products to be manufactured
- **Types and quantities of products** to be manufactured determines how much medicinal cannabis needs to be cultivated



Patient access to medicinal cannabis products

- There may be clinical circumstances where medicinal products that are not registered for general prescription like other medicines would be appropriate for patient care
- Under Australian therapeutic goods legislation, medical practitioners can request access to unregistered medicines for their patients in these circumstances
- Approval can be obtained from the Therapeutic Goods Administration (TGA) under the Special Access Scheme (SAS) or the Authorised Prescriber Scheme.
- Evolving states and territory legislative frameworks are also determining medical prescription and pharmacy dispensing requirements for medicinal cannabis products

Manufacture

How many manufacturing licences will be granted?

- Licences under the **Narcotic Drugs Act** will deal with security and prevention of diversion, in accordance with the Single Convention
- There is no restriction on the number of licences that will be granted
- The number of manufacturers to whom licences will be granted will depend on the needs of patient groups (how much product is required) based on the judgement of appropriate medical practitioners
- Licences under the **Therapeutic Goods Act** will also be required and these deal with the quality of the products reaching patients
- Licences may also be required under **State or Territory legislation**

Manufacture

Licence conditions

- Applicant must demonstrate they will be manufacturing goods for approved patient groups and indications
- A manufacturer can also hold a cultivation/production licence
- In order to reduce security/diversion risk (and comply with Single Convention) cannot stockpile raw material or product – this will be managed by permits
- Manufacturers must only employ suitable staff
- Manufacturers must notify the Secretary of matters relevant to the licence, such as breaches of conditions or matters affecting fit and proper

Cultivation

Obtaining a cultivation licence

- To obtain a licence, the applicant must demonstrate they will be supplying for manufacture but licence does not give a right to cultivate
- Once licensed, a permit will be required to cultivate a crop to the specifications of a contract with the manufacturer
- A contractual arrangement with a licensed manufacturer is required for permit approval
- The ODC aims to be in a position to take licence applications from October 30
- Licence application forms will be made available on the website at www.odc.gov.au prior to this date

Cultivation

Fit and Proper Persons Test

- Convictions or civil penalties against Commonwealth/State/Territory law
- Connections with other persons
- Previous business experience / Sound and stable financial background
- Capacity to comply with licence conditions
- Person is of ‘good repute’

Cultivation

Fit and Proper Persons Test

ODC **must** refuse licence if:

- Not satisfied applicant or relevant business associates are fit and proper
- Satisfied that applicant has committed a serious offence in last 10 years
- Not satisfied applicant will ensure security
- Not satisfied as to location
- Application fee has not been paid
- Applicant hasn’t responded to request for additional information

Cultivation

Requirement to employ suitable persons

- Must be over 18
- Must not have conviction for serious offence in the last five years
- Matters prescribed in regulations regarding criminal record, employment history

Cultivation

Growing / Security Requirements

- Central to Government's policy – ensuring access to *consistent*, *high quality* product
- Obligation under *Single Convention on Narcotic Drugs 1961* to prevent diversion of *any* cannabis grown for medicinal or related scientific purpose
- Consistency with International practice
- Detail to be set out in Regulations

Cultivation

Site security

Possible security principles:

- Prevent and monitor unauthorised access to property where cannabis is grown
- Control access to property
- Access to cannabis to be restricted to only as necessary to undertake duties
- Access to cannabis to be closely monitored (CCTV) / recordings kept to assist investigation of incidents

Cultivation

Site security

Licence conditions will include provisions under guidelines to

- enable security at cultivation and manufacturing sites
- reduce the risk of diversion

Regular and random site inspections will be undertaken to ensure compliance.

Details to be specified in the regulations

Cultivation

Other Conditions

- Obligation to inform employees of obligations
- Activities only undertaken under permit
- Must allow authorised inspectors on to property
- Must hold contracts
- Must notify Office of Drug Control of certain activities

Fees and Charges

Cost recovery model

In accordance with government policy, the licence and permit system is being designed on a cost recovery basis.

Fees will be payable by applicants to cover the costs of:

- processing licence applications
- processing permit applications
- undertaking inspections

Fees and Charges

Cost recovery model

Government and Office of Best Practice Regulation will need to agree to the proposed fees and charges.

- Under Government Cost-recovery guidelines, fees are charged where the direct cost of the activity can be quantified
    - Application fees, for example
- Charges are put in place where the cost cannot be attributed to a single participant, for example, a compliance and monitoring program

Export

Exporting domestically cultivated and manufactured medicinal cannabis products

Exporting of cannabis grown under a licence or medicinal cannabis products is not permitted at this time. As described in explanatory memorandum to the Narcotic Drugs Amendment Bill, the Scheme is:

> *'limiting supply to domestic purposes only initially. This is necessary to establish the system of controls and to ensure they are robust, demonstrating to the international community, in particular the International Narcotics Control Board and potential trading partners, that Australia has an appropriate system for managing the risks of diversion.*
>
> *However, provision is made to allow additional uses through regulations. This will allow the Commonwealth to control the timing on exports subject to successful implementation of a domestically focussed system. Any future export would have to be consistent with the Single Convention."*

Scheduling

What is scheduling?

Scheduling is a process of deciding the levels of control on access that can be applied to a substance, based on the risk of the product. For example:

- Schedule 3 – Pharmacy only medicines
- Schedule 4 – Prescription only medicines
- Schedule 8 – Controlled drug
- Schedule 9 – Prohibited substances

Each schedule has a different level of control about who can dispense them, their labeling requirements and other restrictions

Rescheduling

Delegate's interim decision, April 2016 is to create:

- New Schedule 8 entries for Cannabis and Tetrahydrocannabinols (being extracts, or derivatives of extracts, of cannabis) for human therapeutic use,
- New Appendix D Item 1 entries for Cannabis and Tetrahydrocannabinols substances will only be available from or on the prescription or order of a medical practitioner authorised by states and territories, and
- New Appendix K entries for Cannabis and Tetrahydrocannabinols (substances to be labelled with a warning regarding their sedation potential)

Final decision expected in the next month

Rescheduling

Interim delegate's decision, April 2016 is to create:

For both Cannabis and Tetrahydrocannabinols the Schedule 8 entries are further restricted to substances:

- where the cultivation, production and manufacture of the product containing the substances in Australia is in accordance with the *Narcotic Drugs Act 1967*, or
- where the substances are imported into Australia in accordance with the Customs (Prohibited Imports) Regulations 1956 and any further production or manufacture in Australia is in accordance with the Narcotic Drugs Act, or
- where the products containing the substances are imported into Australia in accordance with those Regulations and no further manufacturing occurs in Australia.

Summary

1. Levels of production of medicinal cannabis and products scheme will be determined by patient demand, based on medical practitioner requests to government for provision through the Authorised Prescriber or Special Access Scheme

2. Based on experience with international demand, production from approx. 2 hectares of greenhouse cultivation would satisfy likely Australian demand

3. Number of cultivators and manufacturers required to meet the likely demand is not yet known

4. Under international conventions, Australia has an obligation to not allow the accumulation of cannabis in excess of domestic requirements

Summary

5. Cultivators and manufacturers will need to adhere to guidelines and regulations. Regular and random inspections will be undertaken to ensure compliance

6. To obtain a cultivation licence, the applicant will need to demonstrate they will be supplying product to a manufacturer

7. Potential manufacturers will need to demonstrate they will be manufacturing goods at an appropriate quality level for approved patient groups and indications

8. Export is not allowed at this time.

Questions